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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,009	11/08/1999	CAROL MORRIS	047763-5010	3768

9629 7590 05/22/2002

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/22/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/367,009

Applicant(s)

MORRIS ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 2 and 4. Further, Applicant amends claims 1 and 3 to recite a method for screening or detecting cancer, comprising detecting the presence of a protein comprising SEQ ID NO:3, wherein the presence of the protein is indicative of the "predisposition" to or the presence of cancer.

Since applicant has elected Groups I and IV, a method for screening or detecting "non-ocular disease" or cancer, and SEQ ID NO:3, for action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the embodiments of amended claims 1, 3 directed to a method for screening or detecting cancer, comprising detecting the presence of a protein comprising SEQ ID NO:3, wherein the presence of the protein is indicative of the "predisposition" to cancer, have been withdrawn from consideration as being directed to a non-elected invention and a kit comprising a nucleic acid encoding a 312C2 protein will be examined. See 37 C.F.R. 1.142(b) and M.P.E.P. 821.03. Newly amended claims 1, 3 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

A marker for cancer is not necessarily a marker for predisposition to cancer because a person who has a predisposition to cancer does not necessarily has cancer.

Accordingly, claims 1, 3, 5-11, SEQ ID NO:3 are being examined, wherein claims 1, 3, 5-11 are examined only to the extent of a method for screening or detecting cancer, comprising detecting the presence of a protein comprising SEQ ID NO:3, wherein the presence of the protein is indicative of the presence of cancer.

The following are the remaining rejections.

OBJECTION

1. Claim 5 is objected to because claim 5 does not further limit claim 1.
2. Claim 10 is objected to because the word "comprising comprising" is redundant.
3. Claim 10 is objected to because the clean copy does not correspond with the corrected version.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

1. Claim 5 is indefinite for the reciting the language "the non-ocular disease", because claim 5 lacks antecedent basis. Said language is not found in claim 1 to which claim 5 is dependent.
2. Claim 9 is indefinite for the reciting the language "the disease indicator or marker", because claim 9 lacks antecedent basis. Said language is not found in claim 3 to which claim 9 is dependent.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claim 5 pertaining to lack of enablement for a method of detecting genetic disorders remains for reasons already of record in paper No.11.

Rejection remains, because Applicant has not answered to the issue of detecting genetic disorders.

REJECTION UNDER 35 USC 102, NEW REJECTION

Claims 1, 3, 5-8, 10-11 are rejected under 35 U.S.C. 102(a) as being anticipated by Molloy, MP et al, 1997, Electrophoresis, 18: 2811-2815.

Claims 1, 3, 5-8, 10-11 are drawn to a method for screening for cancer, comprising separating biomolecules present in a tear sample, and detecting the presence of a protein having a N-terminal amino acid sequence comprising SEQ ID NO:3, using 2D-PAGE and a protein detected in tear having a N-terminal amino acid sequence comprising SEQ ID NO:3.

The specification and the response discloses that the claimed detection is done by detecting a spot on 2D-PAGE of a tear sample, wherein said spot has a MW of 10 KD and a pI of 5.1 (table 2 on page 7). The specification also discloses that partial sequencing of the protein isolated from said spot show a sequence of SEQ ID NO:3 (p.7).

Molly et al teach detection of a spot from 2D-PAGE of a tear sample, wherein said spot has a MW of 10 KD and a pI of 5.2 (spot 16 in table 1, on page 2813). Partial

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sequencing of spot 16 shows a sequence which is identical to SEQ ID NO:3, except for the four C-terminal ^{deletion}6 amino acids (figure 2 on page 2815).

Since 2D-PAGE is not accurate, variation of 0.1 pl is common in the art, especially in view of the fact that the 2D-PAGE done by Molly et al comprises a wide range of pH from 3.5 to 10, as shown in figure 1. Further, although partial sequencing of spot 16 taught by Molly et al shows a sequence which is identical to SEQ ID NO:3, except for the four C-terminal 6 amino acids, said difference could be due to incomplete sequencing. Thus the spot from a tear sample detected by Molly et al using 2D-PAGE seems to be the same as the claimed spot, and thus would inherently comprise SEQ ID NO:3.

The reference does not specifically teach a protein detected in tears having a N-terminal amino acid sequence comprising SEQ ID NO:3. However, the claimed protein appears to be the same as the prior art protein. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Further, because the method of the prior art comprises the same method steps as claimed in the instant invention using the same composition, the claimed method is

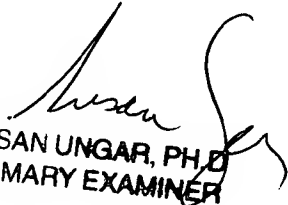
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anticipated because the method will inherently lead to the claimed effects. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

May 18, 2002